Summary of Consensus Reports on Partial Gland Ablation in Prostate Cancer: Indications

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11 consensus statements on focal therapy which include indications (2006 – 2015)

A number of authors involved in more than two of these…

Hashim Ahmed	**6 statements**
Mark Emberton	**5 statements**
Jean de la Rosette	**4 statements**
Scott Eggener	**4 statements**
Thomas Polascik	**4 statements**
Peter Scardino	**3 statements**
Peter Pinto	**3 statements**

One statement covers focal brachytherapy exclusively

Langley S, Ahmed HU, Al-Qaisieh B, Bostwick D, Dickinson L, Veiga FG, Grimm P, Machtens S, Guedea F, Emberton M. Report of a consensus meeting on focal low dose rate brachytherapy for prostate cancer. BJU Int. 2012 Feb;109 Suppl 1:7-16.

One statement covers use of transrectal ultrasound in focal therapy management

Smeenge M, Barentsz J, Cosgrove D, de la Rosette J, de Reijke T, Eggener S, Frauscher F, Kovacs G, Matin SF, Mischi M, Pinto P, Rastinehad A, Rouviere O, Salomon G, Polascik T, Walz J, Wijkstra H, Marberger M. Role of transrectal ultrasonography (TRUS) in focal therapy of prostate cancer: report from a Consensus Panel. BJU Int. 2012 Oct;110(7):942-8

One statement covers use of MRI in focal therapy management

Muller BG, Fütterer JJ, Gupta RT, Katz A, Kirkham A, Kurhanewicz J, Moul JW, Pinto PA, Rastinehad AR, Robertson C, de la Rosette J, Sanchez-Salas R, Jones JS, Ukimura O, Verma S, Wijkstra H, Marberger M. The role of magnetic resonance imaging (MRI) in focal therapy for prostate cancer: recommendations from a consensus panel. BJU Int. 2014 Feb;113(2):218-27.

One statement covers trial RCT design of focal therapy versus standard of care

Ahmed HU, Berge V, Bottomley D, Cross W, Heer R, Kaplan R, Leslie T, Parker C, Relton C, Stephens R, Sydes MR, Turnbull L, van der Meulen J, Vickers A, Wilt T, Emberton M; Prostate Cancer RCT Consensus Group. Can we deliver randomized trials of focal therapy in prostate cancer? Nat Rev Clin Oncol. 2014 Aug;11(8):482-91.

	Round -table	Delphi + round -table	RAND	No. participants	Disciplines represented					
					Uro	Onc	Rad	Path	Trialists	Patients
Donaldson et al 2015			✗	15	✓	✓			✓	
Ahmed et al 2014	✗			65	✓	✓	✓	✓	✓	✓
Reis et al 2014	✗			7	✓	✓	✓	✓		
Van den Bos et al 2014		✗		48	✓	✓	✓			
Muller et al 2014	✗			17	✓	✓	✓			
Smeenge et al 2012				18	✓	✓	✓			
Ahmed et al 2012	✗			30	✓	✓	✓	✓	✓	✓
Langley et al 2012	✗			10	✓	✓	✓	✓		
De la Rosette et al 2010	✗			22	✓	✓	✓	✓		
Eggener et al 2007	✗			14	✓	✓	✓	✓	✓	
Bostwick et al 2006	✗			5	✓	✓	✓	✓		

Is focal therapy an alternative to active surveillance?

YES
4

NO
3

In those 4 statements which state focal therapy might be an alternative to active surveillance, focal therapy was recommended in order to,

- reduce uncertainty of progression on AS (4)

- anxiety of not treating cancer (4)

NCCN risk groups included

- very low risk (1)

- low risk (3)

Is focal therapy an alternative to radical therapy?

YES
6

NO
1

In those 6 statements which state focal therapy might be an alternative to radical therapy, focal therapy was recommended in,

- those men who would benefit from treatment AND

- wished to avoid treatment-related side-effects

NCCN risk groups included

- 'clinically significant' low risk prostate cancer (6)
  - *'high volume' Gleason 6*
  - *>/=0.5ml lesion volume on MRI*
  - *Histological surrogate for 0.5ml lesion*

- *intermediate risk (6)*

- *high risk (due to inclusion of radiological T3a) (3)*

What should be the exclusion and inclusion criteria?

UPPER disease limits

Clinical Factor (upper limit)								
PSA			**Gleason**				**Stage**	
10	15	20	3+3	3+4	4+3	4+4	T2	T3a (radiological)
1	3	2	1	3	1	2	4	3

What should be the exclusion and inclusion criteria?

LOWER disease limits

Clinical Factor (lower limit)					
Minimum no. of biopsies positive		**Minimum cancer core length involvement if Gleason 3+3**		**Minimum lesion volume**	
2	No lower limit	“Clinically significant”	No limit	0.2ml	0.5ml
	3	4	3	1	1

Is index lesion ablation (with no treatment to secondary lesions) an appropriate focal therapy strategy?

YES
5

NO
3

Which localisation techniques can be used for delivery of focal therapy?

Technique	Essential	Optional	Do not use
10-12 core Transrectal biopsies		1	10
Transrectal saturation biopsies		1	9
Template Transperineal Mapping biopsies	2	7	1
Ultrasound techniques			8
Multi-parametric MRI targeted	7	2	1

Conclusions

Whilst there still remains considerable uncertainty and disagreements there are some broad conclusions that can be made…

Over time, consensus statements have moved from advocating focal as an alternative to active surveillance (in low risk disease) to an alternative to radical therapy (in clinically significant low risk and intermediate risk disease)

As a result, the most acceptable criteria are

PSA </=15

and T2 disease

and Gleason 3+3 (‘high volume’)

or Gleason 3+4

Emerging school of thought to place a minimum burden of disease to avoid over-treatment so focal is not used as an alternative to active surveillance in men who will not benefit from any treatment

Over time, consensus statements have advocated the role of multi-parametric MRI and MR-targeted biopsies to rule-in and rule-out clinically significant disease